TITLE 11

DEPARTMENT OF HEALTH

CHAPTER 95

FREESTANDING SURGICAL OUTPATIENT FACILITIES

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§11-95-1 <u>Purpose</u>. The purpose of this chapter is to establish minimum requirements for the protection of the health, welfare, and safety of patients, personnel, and the public in freestanding surgical outpatient facilities. This chapter shall not be construed as lowering standards, ordinances, or rules established by other agencies of government. In all instances the more stringent rules shall apply. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10, 321-11)

§11-95-2 <u>Definitions</u> as used in this chapter:

"Administrator" is the person to whom is delegated
the responsibility for the interpretation and
implementation of the policies and programs established
by the governing body. This person may or may not be
the same as the medical director. The administrator
shall have had suitable and sufficient previous
experience in administration of a medical facility.

"Anesthesia assistant" means a person who has successfully completed a four year educational program for physicians' assistants that includes two years of specialized academic and clinical training in anesthesia.

"Anesthesiologist" means a physician whose specialized training and experience qualify the physician to administer anesthetic agents and to monitor the patient under the influence of these agents.

"Anesthetist" means a certified registered nurse anesthetist.

"Broad service hospital" means a medical facility which is staffed and equipped to provide inpatient medical and surgical care for acute illness, injury, and obstetrics over a period of time longer than twenty-four hours.

"Cardiopulmonary resuscitation" or "CPR" means an emergency first aid procedure that consists of opening and maintaining a patient's airway, providing artificial ventilation by means of rescue breathing, and providing artificial circulation by means of external cardiac compression.

"Chest x-ray" means a full-sized 11" x 14" film taken by the standard technique.

"Dentist" means any person having a valid, unrevoked, license issued by the State of Hawaii to practice "dentistry" as defined by chapter 448, HRS.

"Department" means the department of health of the State of Hawaii.

"Dietitian" means a person who:

- (1) Is registered by the American Dietetic Association; or
- (2) Is eligible for examination to become a registered dietitian.

"Director" means the director of health of the State of Hawaii.

"Freestanding surgical outpatient facility" is a facility developed for the purpose of performing surgical procedures which do not require hospitalization. The procedures are referred to as permitted procedures. Patients admitted to the facility shall remain only long enough to satisfy the objective of the facility and in no case shall they remain longer

than eighteen hours. The facility shall provide for continuous physician's services and for continuous registered professional nursing services, on the premises, whenever a patient is in the facility. shall have an organized administrative structure. facility shall not be an integral part of a broad service hospital and shall not include the offices of private physicians, dentists, or podiatrists. facility is located in the same building with a broad service hospital or with physician's offices, the freestanding surgical outpatient facility shall be a "distinct part", separate from the other medical facilities. A "distinct part" shall be an entire, physically identifiable unit with its own staff, own records, and own equipment. There shall not be any question as to the distinctness of the freestanding surgical outpatient facility from the other medical facilities and services in the same building.

"Governing body" means the individual, individual agency, group, or corporation which has the ultimate responsibility and authority for the conduct of the freestanding surgical outpatient facility and is named in the license as the governing body.

"Licensee" means the governing body to whom the license is issued.

"Licensed practical nurse" means a nurse licensed as such by the State of Hawaii, as defined by chapter 457, HRS.

"Local hospital" means a licensed hospital on the same island as the freestanding surgical outpatient facility.

"Medical director" is the physician who is responsible for planning, organizing, conducting and directing the medical affairs of the facility. The medical director shall currently hold active surgical or anesthesiologist privileges at a local hospital.

"Medical staff" are physicians and dentists authorized by the governing body to practice their profession within the facility.

"Operating room" is a room specifically set aside in which surgical procedures only are performed.

"Outpatient" is a person seeking treatment from the freestanding surgical outpatient facility and who does not stay overnight in the facility.

"Pathologist" means a physician certified or eligible to be certified by the American Board of Pathology.

"Patient" means a person admitted to and receiving care in a freestanding surgical outpatient facility.

"Permitted procedures" are those which:

(1) Are commonly performed on an inpatient basis in hospitals but may be safely performed in a

freestanding surgical outpatient facility;

- (2) Are not of a type that are commonly or safely performed in physicians' offices.
- (3) Are limited to those requiring a dedicated operating room, or suite, and generally requiring a post-operative recovery room or short term convalescent room;
- (4) Do not generally result in extensive blood loss;
- (5) Do not generally require major or prolonged invasion of body cavities;
- (6) Do not generally involve major blood vessels;
- (7) Are not generally of an emergency or life threatening nature;
- (8) Do not include procedures where the surgical operating time plus the post-anesthetic recovery time would normally exceed the planned business hours of the facility.

"Pharmacist" means a "registered pharmacist" as defined by chapter 461, HRS.

"Physician" means a person having in the State of Hawaii a valid license to practice medicine pursuant to chapters 453 or 460, HRS.

"Post-anesthetic recovery time" means that period of time which ends when:

- (1) The patient is alert and oriented and has reached pre-operative mental status; and
- (2) The patient's vital signs have returned to be within normal physiological limits; and
- (3) The patient is able to ambulate without dizziness and has regained pre-operative ambulation ability; and
- (4) The patient is not nauseated or vomiting and can retain fluids by mouth.

"Recovery area" refers to a specific room or space used for post-anesthetic recovery of surgical patients.

"Registered professional nurse" means a person who is licensed as a "registered nurse" in the State of Hawaii, as defined by chapter 457, HRS.

"Tuberculin test" means an intradermal injection of .0001 mg (5 tuberculin units) of purified protein derivative in 0.1 cc of sterile diluent. If the size of any resulting palpable induration at forty-eight hours and seventy-two hours after injection is equal to or greater than 10 mm in its transverse diameter, the reaction to the skin test shall be considered positive. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§26-13, 321-1, 321-10)

§11-95-3 <u>Licensing</u>. (a) No person, or group of persons, shall operate a freestanding surgical

outpatient facility unless it is licensed by the director.

- (b) Any person, or group of persons desiring to operate a freestanding surgical outpatient facility shall apply to the director for a license on forms provided by the department. The director shall issue a license if the proposed facility meets the requirements of this chapter.
- (C) A license, unless abandoned or revoked for just cause, shall be renewed every two years, on date of issue, or of such other interval of time as may be decided by the director. Application for renewal of license shall be made by governing body of the freestanding surgical outpatient facility sixty days prior to expiration date as determined from the license. If application for renewal is not filed, the license shall be cancelled automatically as of the expiration date determined from the license. After receiving notice of deficiencies following an inspection, the facility shall file a plan of correction with the department within ten days. Deficiencies shall be corrected within a reasonable time; failure to do so may result in failure to renew the license.
- (d) A provisional license may be issued for a specified period of time at the discretion of the director, should additional time for correction of deficiencies be deemed advisable. Not more than two successive provisional licenses shall be issued to a particular facility.
- (e) With respect to a particular facility, a specific rule may be waived for a period of one year at the discretion of the director.
- (f) Each license shall be issued to a physical facility and to a governing body. A change in either requires that the department be notified. A new license, at the discretion of the director, may be required.
- (g) The department shall be notified within fifteen days if a new administrator or a new medical director is appointed. A change of administrators or medical directors, at the discretion of the director, may require that a new license be issued.
- (h) The license issued by the director shall be posted in a conspicuous place visible to the public on the premises of the freestanding outpatient surgical facility.
- (i) Appropriate fees, if any, as determined by the director, shall be charged by the department for obtaining a new license or obtaining a license renewal. Prior notice of the amount of the fee shall be provided the licensee.
 - (j) Inspection visits may be made to a licensed

freestanding surgical outpatient facility at any reasonable time without prior notice by authorized staff of the department. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10, 321-11) (Imp: HRS §§91-14, 91-15, 321-1, 321-10, 321-11)

- §11-95-4 <u>License revocation</u>. (a) The director, after due notice, and after suitable opportunity for a hearing, may suspend, revoke, or refuse to issue or renew a license to any governing body because of failure to meet:
 - (1) The requirements of this chapter; or
 - (2) The conditions under which the license was issued.
- (b) Any governing body affected by the director's decision for denial, suspension, or revocation may appeal in accordance with chapter 91, HRS.
- (c) When a license has been revoked, or when a license has not been renewed, an application for a new license shall not be accepted until a period of one year has passed from the time of the revocation or refusal to renew. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10, 321-11) (Imp: HRS §§321-10, 321-11)
- §11-95-5 <u>Administration</u>. (a) The administrative personnel under the direction of an administration shall develop and carry out such administrative procedures as are necessary to achieve the objectives and policies of the governing body.
- (b) The administrator shall establish policies and develop procedures to ensure that all employees are free of infectious diseases. These policies shall include:
 - (1) Pre-employment and an annual health evaluation specifically oriented to rule out infectious diseases shall be conducted by a licensed physician;
 - (2) A tuberculin skin test shall be done. If the tuberculin skin test is significant, a standard chest x-ray and appropriate medical follow-up shall be obtained. A yearly chest x-ray thereafter shall be required for three successive years;
 - (3) If the tuberculin skin test is negative, a second tuberculin skin test shall be done after one week, but not later than three weeks after the first test. The result of the second test shall be considered the baseline and used to determine appropriate follow-up. If the second test is negative, it shall be repeated once yearly thereafter until it

becomes significant;

- (4) Any employee who develops evidence of an infectious disease shall be immediately excluded from any duties relating to food handling and direct patient contact and shall remain excluded until such time as a physician certifies that it is safe for this individual to resume his or her duties. Skin lesions, respiratory tract symptoms and diarrhea shall be considered presumptive, evidence of infectious disease;
- (5) There shall be adequate documentation that all employees have been fully informed about, and understand, paragraphs (1) and (2).
- (c) The administrator, with the active participation of the medical and nursing staff, shall establish policies providing for evaluation of the quality of care provided in the facility. These policies shall provide for identification of problems, analysis or problems to determine cause and documentation of remedial action taken.
- (d) The administrator shall ensure that the facility shall not deny admission to any individual solely on account of race, religion, color, ancestry, or national origin. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10, 321-11) (Imp: HRS §321-10)
- §11-95-6 Anesthesia. (a) General, local, or regional anesthesia shall be administered to patients only by a certified registered nurse anesthetist or by a qualified physician. The anesthesia shall be administered only under the supervision of a licensed physician.
- (b) Flammable anesthetics shall be prohibited except when construction, storage and equipment meet the standards of the National Fire Protection Association Bulletin No. 56G "Standards for the Use of Inhalation Anesthetics in Ambulatory Care Facilities" 1980.
- (c) A person with training and experience in cardiopulmonary resuscitation shall be on the premises of the facility until all patients have been discharged. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)
- §11-95-7 Arrangement for services. Where the facility does not employ a qualified person to render a required and necessary service, it shall have a written contract with an appropriately qualified outside person or provider to perform such service.

 [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp:

- §11-95-8 <u>Communication</u>. (a) Arrangements shall be made to quickly summon additional personnel to any area when needed in an emergency situation.
- (b) There shall be sufficient telephones (not pay telephones) located in separate areas so that at least one is quickly accessible in any part of the facility for emergency use. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)
- §11-95-9 <u>Construction requirements</u>. (a) The facility shall be constructed and maintained in accordance with state and county zoning, building, fire safety, and sanitation laws, ordinances, and rules. New construction and remodeling shall be guided by "Minimum Requirements of Construction & Equipment for Hospital & Medical Facilities" DHEW Publication No. (HRA) 79-14500 as it existed on December 31, 1984.
- (b) The facility shall be accessible to and functional for physically handicapped persons.
- (c) There shall be adequate space to allow free movement of occupants using wheelchairs, walkers, canes and crutches to and from exits, post-operative recovery areas, bathrooms, closets, dressing areas, and common hall areas.
- (d) Provision shall be made for each patient to have use of a lockable closet, dressing cubicle, or dressing room.
- (e) A waiting room of appropriate size shall be provided and toilet rooms, separate from patient toilets, shall be easily accessible to those in the waiting area.
- (f) Suitable dressing areas and toilet facilities for staff use, separate from patient use, shall be provided.
- (g) One or more examining rooms separate from recovery and operating rooms shall be provided.
- (h) Grab bars shall be provided in patient and waiting room toilets. Each bathroom shall provide at least one washbasin and one commode.
- (i) Operating and recovery rooms shall be located so as to prevent through traffic except in the case of emergency. Entrance and exits to these rooms shall be by means of interior doors except for emergency outdoor exit doors which may be provided as needed.
- (j) There shall be adequate scrub-up facilities and work areas for the preparation, sterilization, and storage of instruments and supplies.
- (k) Each patient toilet and bathroom facility shall have a suitable nurses' call system for signalling

the need for assistance.

- (1) Adequate supply of hot and cold potable running water must be supplied at all times. Temperature of hot water at plumbing fixtures used by patients shall be automatically regulated and shall not exceed 110°F.
- (m) Bedpans and urinals shall be available for use as well as suitable methods and equipment for cleaning and sterilizing same.
- (n) In the event that a sexually mixed recovery room is utilized, suitable screens or curtains shall be provided to ensure privacy for each patient.
- (o) Patient beds, wherever located, shall be surrounded by at least three feet of clear floor area.
- (p) All rooms in which patient care is carried out shall be on or above grade level.
 - (q) Floors and walls.
 - (1) Floors shall be of slip resistant material, flush at doorways.
 - (2) Floors shall be of material which does not retain odors.
 - (3) Scatter rugs shall not be used.
 - (4) Walls, floors, ceilings and decorative items in rooms shall be made of material which permit washing, cleaning, and painting.
- (r) Where appropriate, screening of doors and windows shall be provided using screening having sixteen meshes per inch.
- (s) Neither sliding doors nor folding doors shall be used as room or building exit doors. All double-acting doors shall be provided with vision panels.
- (t) The minimum clear width of corridors shall be forty-four inches, except when a general anesthetic is used in the facility. In the latter case, corridors which serve non-ambulatory patients shall be a minimum of eight feet wide.
- (u) Suitable locked storage space shall be available for storing of maintenance equipment and supplies.
- (v) The water supply shall comply with chapter 340E, HRS.
- (w) Ventilation shall comply with chapter 11-39, relating to air conditioning and ventilating.
- (x) Additions, alterations, and all repairs to existing buildings.
 - (1) Where the structure was in use for this type of occupancy prior to the effective date of this chapter, the director may waive or modify any portion of these construction standards, provided the exceptions do not create a hazard to patients personnel or public. In no case

- shall any fire safety standards, as determined by the county fire marshal, be waived or modified;
- (2) Drawings and specifications for all new construction or additions, alterations, or repairs to existing buildings subject to the provisions of this chapter shall be submitted to the licensing branch of the department for review, and a certificate of need where applicable, shall also be submitted.
- (3) Construction shall not commence prior to the department's approval of construction drawings. Specifications shall comply with this chapter, the county fire marshal's rules, and with county building codes and ordinances;
- (4) The department shall review each submittal and advise the applicant, in writing, of its findings, within a reasonable time, with respect to approval, disapproval, or any mandatory changes required;
- (5) Unless construction is commenced within one year of the approval of final construction drawings and specifications, the latter with the previously approved application, shall be resubmitted for review and reapproval;
- (6) Minor alterations which do not affect structural integrity or fire safety and do not change functional operation and do not increase beds or services over that for which the facility is licensed, may be submitted either by freehand drawings or by the more conventional drawings and specifications.
- (y) There shall be appropriately equipped utility rooms, at least one clean and one soiled for each operating suite. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§46-4, 62-34, 64-91, 65-71, 66-71, 70-71, 132-3, 321-10, 340E-1 to 340E-9)
- §11-95-10 <u>Dietetic service</u>. A consultive dietitian shall supervise the preparation and service of whatever special diets may be deemed necessary for the patients to meet the objectives of the facility. There shall be written policies covering whatever dietetic services are deemed necessary by the governing board. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)
- §11-95-11 <u>Disaster planning</u>. Appropriate policies shall be written to provide for cooperation with civil and military authorities in the event of a disaster for

disaster relief under chapter 127, HRS which would require use of the equipment and personnel of the facility staff. [Eff March 3, 1986] (Auth HRS §§321-9, 321-10) (Imp: HRS §321-10)

- §11-95-12 <u>Engineering and maintenance</u>. (a) The facility shall have an appropriate written preventive maintenance program which documents compliance with all life safety codes of the state and county.
- (b) Inspection of all devices essential to the health and safety of patients, personnel, and visitors shall be carried out at sufficiently frequent intervals to ensure operational performance.
- (c) Maintenance and routine repairs to the facility shall not require reviews or approval by the department.
- (d) Appropriate facilities for routine building cleaning shall be provided. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§321-10, 342-17)
- §11-95-13 Governing body. (a) The governing body shall be the supreme authority of the facility, responsible for the management, control and operation of the facility, including the appointment of an administrator and the appointment of a medical director.
- (b) The governing body shall appoint the medical staff and delineate surgical privileges for each physician and dentist.
- (c) The governing body shall specify which of the permitted procedures may be done in the facility.
- (d) The governing body shall specify which procedures may be done in specific areas of the facility.
- (e) The governing body shall be formally organized in accordance with a written constitution and by-laws.
- (f) The governing body shall meet regularly, at least once a year, and the minutes of these meetings shall be kept as a permanent record in the facility. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)
- §11-95-14 <u>Infection control</u>. (a) Definitive policies and procedures governing sterilization techniques shall be developed. All equipment shall be sterilized either by pressurized steam sterilization or gas sterilization. The procedures shall be written and shall include:
 - (1) The technique to be used for a particular instrument or group of instruments;

- (2) The length of time to accomplish sterilization;
- (3) Termperature, time and pressure control levels established for steam sterilization;
- (4) Proper methods of preparation of items for sterilization;
- (5) Shelf storage time for sterile items established;
- (6) Use of sterilizer indicators;
- (7) Use of routine (at least monthly) bacteriological sterilization culture controls.
- (b) Written procedures shall also be developed to provide for:
 - (1) Prohibition of re-use of disposable, one-time use items; and
 - (2) Biologically safe methods of disposal of contaminated items such as needles, syringes, catheters, gloves, pathological wastes, contaminated dressings, and any other contaminated items which might be present in the facility.
- (c) There shall be an infection control committee established to investigate any patient infection and to take prompt and appropriate remedial action to prevent a recurrence. This committee shall consist of a physician and a registered nurse, in addition to others. The facility shall:
 - (1) Maintain permanent written reports of all results of investigations of infections and the remedial action taken;
 - (2) Report promptly to the licensing branch of the department any infectious diseases which they discover that may present a potential hazard to patients, personnel and the public. Included, but not limited to, are the reportable diseases and the occurrence of other diseases in outbreak form; and
 - (3) Provide for adequate patient post-discharge follow-up in order to discover any patient infection and to record same in the files of the infection control committee.
- (d) There shall be a continuous education program provided to all facility personnel on the cause, transmission, prevention, and elimination of infections.
- (e) A policy shall be established for strict control of visitors to prevent their casual access to treatment and post-operative recovery areas. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)

- §11-95-15 <u>Inservice education</u>. There shall be an appropriate inservice education program. This shall include, but not be limited to, annual training in fire prevention, infection control, and accident prevention. There shall be adequate documentation of these educational procedures. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)
- §11-95-16 <u>Laboratory</u>. Sufficient laboratory facilities shall be made available to carry out the objectives of the facility. the laboratory procedures shall be carried out by qualified medical technologists, at least one of whom shall be available as long as a patient is in the facility. Such a laboratory shall be under the supervision of an appropriately qualified physician. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)
- §11-95-17 <u>Laundry service</u>. (a) Provision shall be made for the handling, storage, and transportation of soiled and clean laundry and for satisfactory cleaning procedures.
- (b) Infectious laundry shall be handled in accordance with section 325-7, HRS, relating to potentially infectious laundry. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§321-10, 321-11)
- §11-95-18 <u>Life safety</u>. (a) Facilities licensed under this chapter shall be inspected at least annually by appropriate fire authorities for compliance with state and county laws.
- (b) A written and posted fire control and evacuation plan shall be maintained and kept current. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§132-8, 321-10)
- §11-95-19 <u>Medical director</u>. (a) It shall be the responsibility of the medical director to develop appropriate written policies and procedures to provide the necessary preventive, diagnostic, and therapeutic services to patients in order to achieve the objectives of the facility.
- (b) In cooperation with the administrator, the medical director shall:
 - (1) Develop appropriate staff professional educational programs; and
 - (2) Recommend to the governing body the names of physicians and dentists to be appointed to the medical staff.
 - (c) The medical director shall monitor and

supervise all medical and nursing procedures carried out in the facility, especially including all infection control procedures and policies. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)

- §11-95-20 <u>Medical records</u>. (a) There shall be available sufficient, appropriate qualified staff and necessary supporting personnel to facilitate the accurate processing, checking, indexing, filing, and prompt retrieval of records and record data.
- (b) All patient records shall be considered confidential and the property of the facility which shall secure them against loss, destruction, defacement, tampering, or use by unauthorized persons.
- (c) Patient records shall contain, but not necessarily be limited to, the following information:
 - (1) Prior to surgery, the patient record shall contain the following:
 - (A) Sufficient history, physical examination, x-ray and laboratory data to support the admitting diagnosis and the decision to carry out the proposed procedure;
 - (B) Sufficient history, physical examination, and laboratory data to support the decision as to which anesthetic techniques and medications are to be used during the procedure;
 - (C) Results of all pertinent consultation reports, laboratory and x-ray reports shall be recorded on the chart by the patient's physician. Originals or photocopies of the originals shall be on the chart within forty-eight hours of admission to the facility;
 - (D) Documentation that sufficient attention has been given to:
 - (i) Preventing and preparing for the customary complications of the proposed surgical procedure and the proposed anesthetic procedure;
 - (ii) Preventing and preparing for any
 special hazards confronting a
 particular patient;
 - (E) An informed consent form shall be signed by the patient or the patient's guardian, or patient's parents, and be filed in the chart;
 - (2) Within forty-eight hours following surgery, the patient's record shall contain:
 - (A) An operative note which shall clearly indicate what was found and what was

done;

- (B) An anesthetic note which shall specify the anesthetic techniques and medications used, as well as dosages of the medications. It shall also contain the result of appropriate physiological monitoring during the anesthetic induction, maintenance and recovery period. A record of any untoward development during this period shall also be noted;
- (C) All medications given to or taken by the patient shall be properly recorded in respect to time given, dose, and any response noted;
- (3) A discharge note including the final diagnosis at the time of discharge;
- (4) A copy of the discharge document required in section 11-95-25(d).
- (d) A daily log with monthly summaries of all procedures performed and the disposition of all patients shall be kept by the facility.
 [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)
- §11-95-21 <u>Medical staff</u>. (a) There shall be an organized medical staff that has overall responsibility for the quality of medical care provided to the patients and for the ethical conduct and professional practice of its members.
- (b) The facility shall not permit interns, residents, fellows, graduates of foreign medical schools, or medical students in an appropriate training program to perform a service for which a license is required by the State of Hawaii unless they are at that time licensed by the State of Hawaii as a physician, or else under the direct control and direct supervision of a licensed physician.
- (c) Each member of the medical staff shall have the same surgical privileges at a local licensed hospital as the member seeks at the freestanding surgical outpatient facility. Maintenance of those surgical privileges shall be certified biennially by a local licensed hospital. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§321-10, 453-2)
- §11-95-22 <u>Nuclear medical service</u>. A nuclear medical service, when provided by the facility, shall be under the direction of an appropriately qualified physician. There shall be written policies covering

procedures, and ongoing training, in handling radioactive materials. Where applicable, provisions of chapter 331, HRS, shall apply. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10), (Imp: HRS §§321-10, 331-1 to 331-4)

- §11-95-23 <u>Nursing service</u>. (a) Each facility shall have a nursing staff which shall be directed by the director of nursing. The director of nursing shall be a qualified registered professional nurse who shall be appointed by the administrator with the approval of the governing body. The director of nursing shall develop such nursing service policies and procedures, recruit such nursing personnel, and provide such supervision as is necessary to achieve the objectives of the facility.
- (b) Each facility shall have nursing staff sufficient in number and qualifications to meet the nursing needs of the patients in the facility. There shall be at least one registered nurse present and on duty at all times the facility is open and a patient is present in the facility.
- (c) There shall be an organized written departmental plan which includes objectives, administrative authority, staffing patterns, job descriptions, and responsibilities for each category of nursing personnel.
- (d) There shall be appropriate nursing policies and procedures delineating the scope of services.
- (e) Working personnel in each operating room must include at least one registered professional nurse who shall serve as the circulating nurse.
- (f) If a general anesthetic is used, working personnel in each recovery area shall include at least one registered professional nurse. At least one such person must be physically present and on duty at all times as long as any patients are present in the facility.
- (g) There shall be sufficient personnel on duty, as long as a patient is present in the facility, to provide emergency assistance in any area of the facility without violating subsections (e) and (f). [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§321-10, 457-1)
- §11-95-24 <u>Pathology</u>. Examination of all tissues removed at the time of operation shall be performed by a pathologist. A report of the examination shall be placed in the patient's medical record. Certain permitted procedures may be exempt from this examination

at the discretion of the director. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)

- §11-95-25 <u>Patients' rights and patients' care</u>.

 (a) All patients admitted to the facility shall be under the care of a medical staff member.
- (b) An appropriate medical history and physical examination shall be obtained within seventy-two hours prior to admission of the patient. A record of these procedures shall be on the patient's medical record within the facility prior to induction of any anesthesia or to the performance of any surgical procedure.
- (c) Patients shall be observed in this facility for a reasonable period of time to ensure that no immediate post-operative complications are present. Thereafter, patients shall be discharged at the discretion of the patient's physician. If the patient's physician determines that the post-operative observation period should extend beyond the closing time of the facility, the patient shall be transferred to a hospital.
- (d) At the time of the discharge from the facility, each patient shall be provided with a document including as a minimum the following information.
 - (1) The exact procedure which was performed using accepted medical terminology;
 - (2) The precise names, both generic and proprietory, of the anesthetic used, as well as all other drugs administered in the facility, or given to the patient at the time of discharge;
 - (3) Symptoms of complications which might ensue from the procedures carried on in the facility prior to discharge;
 - (4) Activities to be avoided by the patient;
 - (5) Specific telephone number, or numbers, of the operating physician or dentist, as well as the telephone numbers of at least one suitable back-up physician or dentist;
 - (6) The telephone number and locations of the nearest hospital, or hospitals, to be used by the patient should complications arise. It shall be the responsibility of the operating physician to provide this information;
 - (7) The date and location of the first post-operative check-up to be required.
 - (e) Patient's rights;
 - (1) Written policies regarding the rights and responsibilities of patients during their stay in the facility shall be established by the

- governing body and shall be made available to the patient, guardian, next of kin, sponsoring agency, and to the public;
- (2) All patients have the right to obtain from their physician complete current information concerning their diagnosis, prognosis, and treatment in terms that can be reasonably expected to be understood. When it is not medically advisable to give such information to the patient, the information shall be made available to an appropriate person on the patient's behalf. The patients are entitled to know, by name, the physician coordinating their care, as well as the physician who actually performs any surgical procedure;
- (3) Each patient or guardian is entitled to receive sufficient information to give informed consent prior to the start of any procedure or treatment. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)
- §11-95-26 <u>Penalty</u>. In addition to any other appropriate action to enforce this chapter, the director may initiate procedures for invoking penalties as provided in chapter 321, HRS. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§321-10, 321-18)
- §11-95-27 <u>Pharmaceutical service</u>. (a) Medicines shall not be administered to patients unless ordered by a physician. The orders shall be in writing or, if given orally, shall be promptly reduced to writing and signed by the physician prior to discharge of the patient.
- (b) Medicines maintained in the facility shall be appropriately stored and safeguarded against access by unauthorized persons. Appropriate records shall be kept of the disposition of all medications.
- (c) If medications are dispensed by the facility, the dispensing shall be under the supervision of a pharmacist who shall be employed either full time or part time as deemed appropriate by the director.
- (d) Each facility shall maintain reference sources for identifying and describing medications.
- (e) Medicine shall be administered only by a licensed nurse or physician.
- (f) Blood, blood products, and parenteral solutions shall be administered only by physicians, or registered nurses.
 - (g) Adverse drug reactions shall be reported

immediately to the physician responsible for the patient and this report shall be documented in the medical record. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§321-10, 329-38, 461-11, 461-14)

- §11-95-28 <u>Radiology service</u>. The radiology service shall be directed by a qualified radiologist and be staffed by qualified technical personnel. There shall be written policies governing all radiological procedures. Sufficient diagnostic and therapeutic radiological equipment shall be available to satisfy the objectives of the facility. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§321-10, 466J-4)
- §11-95-29 <u>Social work service</u>. At the time of discharge from the facility, each patient, or another suitable person, shall be provided with appropriate information concerning community services which are available for home care needs. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)
- §11-95-30 <u>Surgical facilities</u>. (a) Each operating room and surgical suite shall be appropriately equipped and supplied for the types of procedures to be performed.
- (b) Each recovery area shall be appropriately equipped and supplied for the post-anesthetic recovery of surgical patients.
- (c) The following equipment and supplies shall be available in all surgical and recovery areas:
 - (1) Cardiopulmonary resuscitative drugs and intubation equipment;
 - (2) Cardiac monitor;
 - (3) Appropriate oxygen and suction equipment;
 - (4) Defibrillator;
 - (5) Suitable anesthetic equipment customarily available for all planned anesthetic procedures;
 - (6) Thorocotomy set including a chest tube and a water seal bottle; and
 - (7) Tracheostomy set. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)
- §11-95-31 <u>Transfer agreement</u>. The facility shall establish transfer agreements which will expedite the transfer of patients to hospitals when needed. There shall be documented evidence that a local hospital has

agreed to admit without delay, patients from the facility, should the staff of the facility feel this is advisable. [Eff March 3 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§127-9, 321-10)

§11-95-33 through §11-95-99 reserved.

§11-95-100 <u>Severability</u>. If any provision of this chapter or the application thereof to any person or circumstances is held invalid, the remainder of this chapter or the application of the provisions to other persons or circumstances shall not be affected thereby. [Eff March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§321-9, 321-10)